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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,926	06/11/2001	Joelle Thonnard	BM45330	9849

25308 7590 08/13/2002

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/13/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/762,926

Applicant(s)

THONNARD, JOELLE

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35,37,39-42,57 and 59 is/are pending in the application.
- 4a) Of the above claim(s) 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-35,37,39-42 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's preliminary amendment of February 11, 2002, paper No. 9 is acknowledged. Claims 36, 38, 43-56, 58 and 60-68 were canceled by the applicant as being drawn to the non-elected invention.

Election/Restrictions

2. Applicant's response to restriction requirement of November 28, 2001, paper No. 7 is acknowledged.

Applicant elected group I (claims 29-35, 37, 39-42 and 57) without traverse which are drawn to polypeptides, fusion protein and method of producing the polypeptide. Further with respect to the requirements for election of species, Applicant elected SEQ ID NO: 4 without traverse.

3. Claims 29-35, 37, 39-42, 57 and 59 are pending. Claim 59 is withdrawn from consideration as being drawn to non-elected group II. (Note applicant canceled all other claims, which were drawn to non-elected inventions except claim 59).
4. Claims 29-35, 37, 39-42 and 57 are under consideration.

Abstract

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Information Disclosure Statement

6. The references cited in the PCT search report have been considered, but will not be listed on any patent resulted from this application because they were not provided on a separate list in compliance with 37 CFR 1.98 (a) (1). In order to have the references printed on such resulting

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patent, a separate listing on a PTO-1449 form, must be filed within the set period for reply to this office action.

Priority

7. This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a 371 of Application No. PCT/EB99/05989, filed 08/13/1999 and claims priority to United Kingdom application No. 9818004, filed 08/18/1998." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Drawings

8. The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 948.

Specification

9. The disclosure is objected to because of the following informalities:

A brief description of drawings is not mentioned in the description. A reference in the specification to the brief description of the drawing(s) is required as set forth in 37 CFR 1. 74

The use of the trademarks Qiagen and Novex (specification pages 52-53) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 29-35, 37, 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

Claims 29-35, 37, 39-42 recite a polypeptide comprising a fragment of SEQ ID NO: 4 or variants thereof with respect to % identity or numbers of substitutions/deletions/additions where said fragment has the ability to generate antibodies to SEQ ID NO: 4. Some claims are further limited to specific lengths 15 or 20 amino acid long). The same claim alternatively recite polypeptides comprising % identity or substitutions/deletions/additions of SEQ ID NO: 4.

The specification and the claims do not indicate what distinguishing attribute are shared by the members of the genus. Thus the scope of the claims include numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, SEQ ID NO: 4 is insufficient to describe the genus of 90% variants or fragments thereof. Applicant's recitation that the fragment or variant has the ability to generate antibodies to SEQ ID NO: 4 is noted, however this is a function of any peptide. Every peptide of at least 10 amino acid is capable of eliciting an antibody, and if the full length protein is linearized the elicited

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antibody will also bind the full length protein. Thus applicant has not described a function, which is shared by the full length or fragments thereof of SEQ ID NO: 4, which would adequately describe the genus. One skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of the variants. Thus applicant was not in possession of the claimed genus.

None of these fragments meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 37, 42 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is unclear in reciting “ A fusion protein comprising the isolated polypeptide of claim 29”. It is not clear what is the fusion partner of this fusion protein?

Claim 57 is indefinite as being dependent from canceled claim 56.

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It is not clear what applicant intends in reciting the phrase “ under condition sufficient for the production of the encoded polypeptide” in claim 57.

It is not clear what applicant intends in reciting the phrase “ suitable composition” in claim 42.

It is not clear what applicant intends in reciting the phrase “ suitable carrier” in claim 42.

Art Rejections

12. Note: Prior to setting forth the art rejections it is noted that the priority document United Kingdom 9818004.5 filed 8/18/1998 does not have written description support for the new claimed invention and further does not meet the requirements with respect to enablement. Accordingly, the prior art date is the International filing date of 8/13/1999. Should applicant wish to dispute the assignment of the date of the invention, he/she should point to the sections in the priority document for written description support for the now claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 29, 37, 39, 40, 41, are rejected under 35 U.S.C. 102(b) as being anticipated by Legrain et al. (Gene, Vol. 130, pp. 73-80, 1993).

The claims are drawn to an immunogenic fragment of amino acid that matches an aligned contiguous segment of SEQ ID NO: 4 with no more five single amino acid substitution.

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Legrain et al. teach immunogenic fragments of amino acid that matches an aligned contiguous segment of SEQ ID NO: 4 with no more five single amino acid substitution. (see fragments in residues 46-49 and residues 464-467 as indicated in Accession Number JN0819 (see attached sequence alignment). The fragments were isolated from outer membrane protein of *Neisseria meningitidis* B16B6 and M982 strains (see page 74). The prior art teaches the claimed products.

Since the office does not have the facilities for examining and comparing applicants' products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

14. Claims 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Legrain et al. (Gene, Vol. 130, pp. 73-80, 1993).

The claim is drawn to a process of producing an isolated polypeptide comprising:

- Culturing the host cell
- Recovering the polypeptide

Legrain et al. teach a process of producing an isolated polypeptide comprising:

- Culturing the host cell
- Recovering the polypeptide

(see page 74 under purification of Tf-binding proteins and Cloning of *tbp1* and *tbp2*).

The prior art teaches the claimed process.

Since the office does not have the facilities for examining and comparing applicants' process with the process of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the process of the prior art (i. e., that the process of prior art does not possess the same steps, material structure and functional characteristics of the claimed process). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

15. Claims 29-32, 37, 39, 40- 41, are rejected under 35 U.S.C. 102(b) as being anticipated by Bash et al. (Infection and Immunity, Vol. 63, No. 4 pp. 1484-1490, 1995).

The claims are drawn to an immunogenic fragments of amino acid that matches an aligned contiguous segment of SEQ ID NO: 4.

Bash et al. teach immunogenic fragments of polypeptides isolated from outer membrane protein of *Neisseria meningitidis*. Bash et al. teach antigenic epitopes isolated from 14 different serotypes and strains of *Neisseria meningitidis* (see abstract and tables 1 and 2). The prior art teaches the claimed invention. Fragments comprising 15 or 20 amino acid matching an aligned contiguous segment of SEQ ID NO: 4 would be inherent in the outer membrane proteins taught by the prior art (see figures 1 and 2, page1486).

Since the office does not have the facilities for examining and comparing applicants' products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

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Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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August 4, 2002


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